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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,266	08/31/1999	DAVID J. BRAYDEN	99.1080.US	1219

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/386,266	BRAYDEN, DAVID J.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 08/09/04 in response to the final Office Action mailed 04/26/04.

Status of Claims

2) Claims 1-6 and 15-20 have been canceled via the amendment filed 08/09/04.

Claims 35 and 41 have been amended via the amendment filed 08/09/04.

Claims 35-46 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

5) The rejection of claims 1-6 and 15-20 made in paragraph 6 of the Office Action mailed 04/26/04 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

6) The rejection of claims 35, 36, 41, 42 and those dependent therefrom, made in paragraph 7 of the Office Action mailed 04/26/04 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn upon further consideration and in light of Applicants' arguments.

7) The rejection of claims 1-4, 6 and 15-18 made in paragraph 8 of the Office Action mailed 04/26/04 under 35 U.S.C § 102(b) as being anticipated by Maloy *et al.* (*Immunology* 8: 661-667, 1994), is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 1-4, 6 and 15-18 made in paragraph 8 of the Office Action mailed 04/26/04 under 35 U.S.C § 102(b) as being anticipated by Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996 - already of record) as evidenced by Garcon *et al.* (US 6,372,227, already of record) or Rook

et al. (US 6,056,964, already of record), is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 5 and 19 made in paragraph 10 of the Office Action mailed 04/26/04 under 35 U.S.C § 103(a) as being unpatentable over Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996, already of record) as applied to claims 1 or 15 above and further in view of Cahill *et al.* (*Vaccine* 13: 455-462, 1995, already of record) and Mills *et al.* (*Infect. Immun.* 61: 399-410, 1993, already of record), is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 20 made in paragraph 11 of the Office Action mailed 04/26/04 under 35 U.S.C § 103(a) as being unpatentable over Nixon *et al.* (*Vaccine* 14: 1523-1530, 1996, already of record) as applied to claim 15 above and further in view of Jones *et al.* (*J. Biotechnol.* 44: 29-36, 1996, already of record), is moot in light of Applicants' cancellation of the claim.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office Action. The new rejections are necessitated by Applicants' amendments to the claims, which changes the scope of the claims. The base claims 35 and 41 do not now require the administration of an antigen to a subject and the presence of an antigen in the vaccine formulation respectively.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

11) The amended claims 35 and 41 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 35, as amended, is drawn to a method of inducing a T_H1 polarised immune response 'to an antigen' comprising parenterally administering to a subject microparticles sized to have the recited average diameter. The now claimed method does not require the administration of 'an antigen'. Similarly, claim 41, as amended, is drawn to a vaccine formulation for enhancing the T_H1 immune response 'to at least one antigen' adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles sized to have the recited average diameter. The now claimed vaccine formulation is not required to comprise 'at least one antigen'. There appears to be no descriptive support within the specification, as originally filed, for such a method of inducing a T_H1 polarised immune response 'to an antigen'

that does not include the parenteral administration of 'an antigen', or that includes only the parenteral administration of the microparticles of the recited average diameter. Similarly, there appears to be no descriptive support within the specification, as originally filed, for a vaccine formulation for enhancing the T_H1 immune response 'to at least one antigen' which vaccine formulation does not comprise 'at least one antigen', or comprises only a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles sized to have the recited average diameter. Therefore, the new limitations in the instant claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the claimed invention identified above, or to remove the new matter from the claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

12) Claims 35-46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 35 is vague, indefinite and/or confusing in the limitation: 'method of inducing a T_H1 polarised immune response to an antigen comprising parenterally administering to a subject microparticles sized such that the average diameter of the microparticles is from about 2.2 μm to about 4.3 μm'. It is unclear how one can induce a T_H1 polarised immune response 'to an antigen' merely by the parenteral administration to a subject of microparticles sized to have the recited range of average diameter, i.e., without the administration of 'an antigen' itself. Are the recited microparticles serving as 'an antigen' in the claimed method? The claim simply does not make sense. (b) Claim 41 is vague, indefinite and/or confusing in the limitation: 'vaccine formulation for enhancing the T_H1 immune response to at least one antigen ... for parenteral administration comprising a ... carrier and .... microparticles sized such that the average diameter of the microparticles is from about 2.2 μm to about 4.3 μm'. It is unclear how a vaccine formulation

meant for enhancing the T_H1 immune response to 'at least one antigen' can comprise merely a pharmaceutically acceptable carrier and microparticles as recited, i.e., without comprising 'at least one antigen'. Are the recited microparticles serving as 'at least one antigen' in the claimed formulation? The claim simply does not make sense.

(c) Claim 37 has improper antecedence in the limitations: 'method of Claim 35, wherein **the** biodegradable polymer comprises' [Emphasis added]. Claim 37 depends from claim 35, which as amended, does not recite any 'biodegradable polymer'.

(d) Claim 43 has improper antecedence in the limitations: 'vaccine formulation of Claim 41, wherein **the** biodegradable polymer comprises' [Emphasis added]. Claim 43 depends from claim 41, which as amended, does not recite any 'biodegradable polymer'.

(e) Claim 45 is vague and indefinite in not having proper antecedence for the limitation: 'the antigen'. Claim 45 depends from claim 41, which does not recite 'an antigen', but recites 'at least one antigen'. For proper antecedence, it is suggested that Applicants replace the limitation with --the at least one antigen--.

(f) In line 4 of claim 41, for clarity, it is suggested that Applicants distinctly claim the subject matter by replacing the recitation 'microparticles sized' with the limitation with --microparticles, wherein the microparticles are sized--.

(g) Claim 45 is indefinite and confusing in the recitation: 'vaccine formulation of Claim 41, wherein the antigen comprises a *B. pertussis* antigen'. Claim 45 depends from claim 41, which is drawn to a vaccine formulation that does not comprise any antigen, but comprises only a pharmaceutically acceptable carrier and microparticles.

(h) Claim 46 is indefinite and confusing in the recitation: 'vaccine formulation of Claim 41, wherein .... each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer'. Claim 46 depends from claim 41, which is drawn to a vaccine formulation that does not comprise any antigen entrapped or encapsulated by a biodegradable polymer, but only a pharmaceutically acceptable carrier and microparticles.

(i) Claims 36-40 and 41-46, which depend directly or indirectly form claim 35 or claim 41, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

13) Claims 35-46 stand rejected.

14) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

16) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor,

Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

October, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER